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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,465	10/06/2000	Daniel A. Japuntich	48317US028	8753

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EXAMINER	
DEMILLE, DANTON D	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
12/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	09/680,465	JAPUNTICH ET AL.	
	Examiner	Art Unit	
	Danton DeMille	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-52,54-57,60-63 and 66-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-52,54-57,60-63 and 66-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/13/7, 7/7/6
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the valve cover further including a surface that holds the flexible flap in the abutting relationship against the flap-retaining surface as recited in claims 66 and 67 for example, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention.

The specification recites on page 10 that the flexible flap preferably provides a leak-free seal according to the standards set forth in "30 C.F.R. § 11.183-2 (July 1, 1991)" however, it is unclear exactly what characteristics of the seal are being described. This would appear to be an improper "incorporation by reference". Making reference to specific claimed features by way of reciting reference numbers to an external document is not a valid "incorporation by reference". See 37 CFR 1.57.

Claims 41 and 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not adequately described in the specification as set forth in the above rejection to the specification.

Claim Rejections - 35 USC § 112

Claims 41, 70 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the scope of claims 41 and 70 is because it is not clear what specific structural limitations are being referred to by 30 C.F.R. § 11.183-2.

Claim 82 depends upon a cancelled claim and therefore the scope of the claim is unknown.

Double Patenting

Claims 84, 87, 35-52, 54-57, 60-63, 83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,460,539 in view of Cover '949.

The patent claims recite the mask body, the exhalation valve including the valve seat and a flexible flap having a cantilevered flap retaining surface and a free end. While the patent claims appear silent with regard to the details of the seal ridge, a plurality of openings and the curved profile of the flexible flap in a closed position, Cover teaches such details. It would have been obvious to one of ordinary skill in the art to modify the patent claims in view of Cover to include the seal ridge to increase the reliability of the seal, the plurality of openings to increase the structural integrity of the seal and the curved profile to increase the bias of the flap to the seal to maintain the seal in the closed position.

As to claims 35-36, it would have been obvious to fabricate the valves by any well known technique which is known to be employed in the fabrication of plastics and rubber including the technique of injection molding. Further, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964,966 (Fed. Cir. 1985). Inasmuch as injection molding is a widely employed technique in the fabrication of plastic and rubber materials, it would have

been obvious to make the valve of Simpson et al. from a variety of well known techniques including injection molding.

As to claim 37, Cover teach the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 34-44). The seal (fig 10) of Cover is illustrated as being concavo-convex and substantially uniform. Since the flexible flap 37 of Cover is disclosed of being made from rubber and since known physical characteristics of rubber include flexibility and resiliency, the flap 37 of Cover being made from rubber is fully capable of providing the recited function of "...capable of allowing the flap to display a bias towards the seal surface.".

As to claim 38, the flexible flap 37 of Cover is disclosed as being made of rubber (i.e. a known elastomeric material) and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claims 39 and 42, the flexible flaps 37 of Cover are disclosed as being made of rubber and polyisoprene is one common example. It would have been obvious to make the flexible flap from any well known rubber including polyisoprene as mere substitution of one well known rubber for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claims 40 and 41, the degree of a seal between the valve flap and valve seat sealing surface can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one ordinary skill in the art would strive to make a face mask in accordance with at least minimum current government

standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 43-46, 48, 49, the particular dimensions, the particular material including the hardness of the material of the flexible flap 37 of Cover can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency. One of ordinary skill would have recognized that the particular dimensions and the particular material including hardness of the material would have been dependent upon the airflow requirements of a group of wearers, that is, an adult would require a mask and valve of a size and material that is capable of handling respiratory airflows typical of adults whereas a child or an adult with a compromised respiratory system would require a mask and valve of a size and material that is capable of handling lesser respiratory airflows.

As to claim 50, while Cover is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 51, the flange 31 against which the valve flap is secured in Cover is illustrated as being 360 degrees around the valve seat.

As to claim 52, it would appear that the exhaled gas is directed downwardly in Cover.

As to claim 54-56, while Cover appears silent with regard to the particular volume of a wearer's exhalation exiting the exhalation valve, it is submitted that since the exhalation valve is

expressly disclosed as opening in response to a wearer's exhalation, the valve of Cover is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Cover.

As to claim 57, it would appear the exhalation valve is substantially opposite to a wearer's mouth and since the flap 37 is secured to the valve body at only one point on the perimeter of the valve body it would appear to comprehend the claimed cantilever fashion.

As to claims 60, 61, 62, 63, the pair of openings 29 of Cover would appear to be directly disposed in the path of the fluid flow from the openings 35 in the valve. The portion of the impermeable cover that is between the two openings 29 would also appear to be a cross member.

Claims 84, 87, 35-52, 54-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,460,539 in view of Cover '949.

Cover teaches the details of the seal ridge, a plurality of openings and the curved profile of the flexible flap in a closed position. It would have been obvious to one of ordinary skill in the art to modify the patent claims in view of Cover to include the seal ridge to increase the reliability of the seal, the plurality of openings to increase the structural integrity of the seal and the curved profile to increase the bias of the flap to the seal to maintain the seal in the closed position.

Regarding claims 35-52, 54-57, the same arguments applied above relative to Cover would apply here as well.

Claims 84, 87, 35-52, 54-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,509,436 in view of Simpson et al. '516.

The patented claims include the details of the valve seat, seal ridge, an orifice, a flap retaining surface, the non-centrally disposed stationary flap retaining portion, the curved profile and the biased seal. The claims appear silent with regard to the mask body. It would have been obvious to one of ordinary skill in the art to modify the patent claims to include the details of the cup shaped mask as taught by Simpson to provide such conventional details.

Regarding claims 35-52, 54-57, the same arguments applied above relative to Cover would apply here as well.

Claims 84-90, 35-52, 54-57, 60-63, 66-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-87 of copending Application No. 09/678580 in view of Cover '949.

The pending claims recite everything but the details of the seal ridge. Cover teaches a seal ridge 36 to provide a more secure seal between the flap and the sealing surface. It would have been obvious to modify the pending claims to include a seal ridge as taught by Cover to provide a more secure seal between the flap and the sealing surface.

This is a provisional obviousness-type double patenting rejection.

Claims 84-90, 35-52, 54-57, 60-63, 66-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33, 35-42, 44, 46, 49, 50, 55-59, 64-68 of copending Application No. 09/837714 in view of Cover '949.

The pending claims recite everything but the plurality of openings. Cover teaches the plurality of openings in the valve seat. It would have been obvious to modify the pending claims to include a plurality of openings as taught by Cover to provide a more structurally stable valve seat.

This is a provisional obviousness-type double patenting rejection.

Claims 84-90, 35-52, 54-57, 60-63, 66-83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7117868 in view of Cover '949.

The patented claims recite everything but the curved profile of the flap. Cover teaches the flap having a curved profile. It would have been obvious to modify the pending claims to include a flap having a curved profile as taught by Cover to bias the flap against the valve seat for a more secure seal.

Claim 84, 87, 35-52, 54-57, 60-63, 83 rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. '516 in view of Cover '949.

Simpson teaches, for example, a filtering mask that includes a cup shaped mask body 1 and an exhalation valve 12 positioned on the mask body substantially opposite to a wearer's mouth. The exhalation valve includes a valve seat that the flexible flap 15 rests against when it closes the plurality of openings 16. The valve seat also has a flap retaining surface that is non-centrally disposed on the top portion of the valve as shown in figure 2. While Simpson may not teach the details of the seal ridge and the curved profile of the flap, Cover teaches this option.

Cover teaches an exhalation valve in figures 9-11 for example. The valve seat 30 includes a seal ridge 36 that includes the seal surface and an orifice 35 that is surrounded by the

seal ridge including a plurality of openings 35. Cover also teaches a flap retaining surface near 39 where the flap 37 is in an abutting relationship that is non-centrally disposed. That portion of the peripheral edge of the flap adjacent the flap retaining surface near 39 would be the stationary portion. That portion of the flap would remain fixed or stationary in an abutting relationship with the flap retaining surface. Figure 5 shows the location of the pin 39 in close enough proximity to the perimeter of the flap that the flap is deformed by the attachment to the pin that would apply pressure to the flap out to the perimeter of the flap preventing any movement during exhalation. This arrangement is similar to applicant's pin location near the perimeter of the flap and therefore would perform the same function as the instant invention.

Cover also teaches the flap has a concavo-convex profile in a closed position biasing the flap toward the seal surface to keep the flap in a closed position. It would have been obvious to one of ordinary skill in the art to modify Simpson to use the exhaust valve of Cover as an obvious equivalent alternative exhaust valve for performing the same function.

Regarding claim 87, there appears to be no unobviousness to the number of openings in the valve. Simpson appears to teach four openings as shown in figure 1. Such would have been an obvious provision.

As to claims 35-36, it would have been obvious to fabricate the valves by any well known technique which is known to be employed in the fabrication of plastics and rubber including the technique of injection molding. Further, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964,966 (Fed. Cir. 1985). Inasmuch as injection molding is a widely employed technique in the fabrication of plastic and rubber materials, it would have been obvious to make the valve of Simpson et al. from a variety of well known techniques including injection molding.

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criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one ordinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

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As to claim 54-56, while Cover appears silent with regard to the particular volume of a wearer's exhalation exiting the exhalation valve, it is submitted that since the exhalation valve is expressly disclosed as opening in response to a wearer's exhalation, the valve of Cover is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Cover.

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As to claims 60, 61, 62, 63, the pair of openings 29 of Cover would appear to be directly disposed in the path of the fluid flow from the openings 35 in the valve. The portion of the impermeable cover that is between the two openings 29 would also appear to be a cross member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access

to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Danton DeMille/

4 December 2007

Danton DeMille
Primary Examiner
Art Unit 3771